appropriate action as deemed necessary to protect the invention of Groups II-VIII. By canceling the claims in Groups II-VIII, Applicants do not hereby waive any rights in the inventions of Groups II-VIII.

Appendix A at page 9 of this Response lists all pending claims for Examiner's convenience.

RESPONSE TO REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1-14, 17, and 18 are rejected under 35 U.S.C. § 112, first paragraph, as lacking sufficient written description. In making the rejection, the Examiner states the following:

> Applicant's arguments have been fully considered but have not been found to be persuasive. The Examiner agrees that Applicant has described a method for producing four amino-terminally-modified proteins. Such methods are standard in the art. As stated in the previous office action, however, Applicant has disclosed the functional characteristics of one species, while the claims are drawn to a genus of modified chemokines.
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> In determining that two species of chemical compound were insufficient to describe a genus, *In re Gostelli* does not set forth requirements for written description. *Vas-Cath, Inc. v. Mahurkar* uses the phrase "reasonable clarity" and explains that the purpose of written description is to convey to those of skill that he or she was in possession of the claimed invention at the time of filing. The disclosure of how to make four examples and of the functional characteristics of one does not serve to convey with "reasonable clarity" that Applicant was in possession of the invention as broadly claimed. Applicant has disclosed the functional characteristics of one species. As stated in the previous Office Action, there is insufficient guidance to allow one of skill to identify other species that would have the same functional characteristics as the disclosed species. Thus Applicant has not described the essential characteristics of the claimed genus.
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> ....
>
> Here, the chemokines are not structurally related, the claimed modifications are not structurally related, and the claims, since they are drawn to compositions comprising the modified chemokines, are not limited to particular modified chemokines, and as discussed in the previous office action, the art is unpredictable.

Applicants respond as follows:

Applicants respectfully disagree with Examiner's conclusion that the subject matter of claims 1-14, 17, and 18 is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention, at the time the application

was filed.

Whenever the issue of written description arises during the prosecution of a patent application, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed. The subject matter of the claim *need not be described literally*. M.P.E.P. § 2163.02 (emphasis added). In examining the sufficiency of a patent application disclosure to support a generic or subgeneric claim, "it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.'" *In re Grimme*, 124 U.S.P.Q. 499, 501 (C.C.P.A. 1960).

Examiner states that although the claims are drawn to a genus of modified chemokines, "there is insufficient guidance in the disclosure to allow one of skill to identify other species that would have the same functional characteristics as the disclosed species." *Office Action* at p.3. However, rejected claims 1-14, 17 and 18 are drawn to a specifically enumerated set of amino-terminal modified chemokines. In other words, the chemokines used as the starting material for the amino-terminal modified compositions of the present invention are well known to one of ordinary skill in the art, i.e, their nucleotide and amino acid sequences are well known to those of ordinary skill. Upon reading the method set out in Example 1 at page 42 of the Specification, one of ordinary skill in the art would readily recognize that Applicants were in possession of the invention claimed in Claims 1-14, 17 and 18. Example 1 describes the process of attaching an N-terminal moiety to the amino-terminal end of a chemokine. The process is described in great detail and can be easily adapted for use with other

chemokines by one of ordinary skill. Example 1 at page 43 further describes the detailed purification of an exemplary amino-terminal modified chemokine, which can be adapted for use with other amino-terminal modified chemokines. In sum, the disclosure in the patent application provides the level of written description necessary for one of ordinary skill to recognize that the Applicants were in possession of the subject matter of the invention at the time of filing of the application.

Examiner's statement that "there is insufficient guidance in the disclosure to allow one of skill to identify other species that would have the same functional characteristics" is incongruous in light of the fact that claims 1-14, 17 and 18, are drawn to the composition comprising modified chemokines, rather than to their functional characteristics. One of ordinary skill in the art would not be required to "identify other species that would have the same functional characteristics as the disclosed species" because claim 1 reads on a specific set of modified chemokines, the chemokine components of which are well know in the art. By requiring that the functional characteristics of the claimed compositions be disclosed, Examiner has impermissibly read a (functional) limitation into the claims. The scope of pending claims 1-14, 17 and 18 read on compositions comprising a chemokine (from an enumerated list) that is modified at its amino-terminus. The invention as claimed does not require knowledge of the structural and functional characteristics of the amino-terminal modified chemokines in order to practice the claimed invention. Applicants have provided sufficient detail in the specification in Example 1, which would enable one of ordinary skill to recognize that Applicants were in possession of the subject matter of the invention in claims 1-4, 17, and 18.

Claims 1-14, 17, and 18 are also rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement commensurate with the scope of the claims. In making the rejection, the Examiner states the following:

> Applicant has not, ..., provided sufficient guidance for one of skill to use the invention commensurate with the scope of the claims. Applicant has provided working examples for one modified chemokine. Thus the identification of one member of this diverse genus does not provide sufficient guidance by which other species that would function as claimed could be identified; it is clear that the results of the claimed modification are not predictable.
>
> ....
>
> Since there are many possible encompassed species, since Applicant has disclosed the functional characteristics of only one, and since Applicant has not provided any guidance by which other functional species might be identified, and since the art teaches that the outcome of such modifications is not predictable, one of skill would not be able to predict which of the many possible species that meet the limitations of the claims would actually be functional that renders the required experimentation undue.

Applicants respectfully disagree with Examiner's conclusions that the specification does not enable a person skilled in the art to practice the invention commensurate in scope with the claims. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent *coupled with information known in the art*, without undue experimentation. *United States v. Telectronics, Inc.*, 8 U.S.P.Q.2d 1217, 1233 (Fed. Cir. 1988) (emphasis added). A patent need not teach and preferably omits what is well known in the art. *In re Buchner*, 18 U.S.P.Q.2d 1331. 1332 (Fed. Cir. 1991).

All that is required to make and use the invention claimed in claims 1-14, 17 and 18 is knowledge of the nucleotide sequence of the list of chemokines enumerated in claim 1, along with a method of producing the amino-terminal modified form of one of the enumerated chemokines. The

chemokines enumerated in claim 1 were well known in the art at the time of Applicants' invention. *See Specification* at pages 2-3. Therefore, Applicants are not required to provide in their disclosure what is already well known in the art.

As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 166 U.S.P.Q. 18, 24 (C.C.P.A. 1970). Applicants have followed the mandate of *In re Fisher*, and provided a detailed example (Example 1) for making and using the claimed invention. The methods described in Example 1 can be used for all of the enumerated chemokines in claim 1 using the knowledge of the nucleotide sequences of the chemokines described in the prior art, together with the method of modifying the amino-terminal end of the chemokine as discussed in Example 1 of the Specification.

As stated earlier, the invention as claimed *does not require* knowledge of the structural and functional characteristics of the amino-terminal modified chemokines in order to practice the claimed invention. Therefore, Applicants find Examiner's rejection of the claims as lacking enablement because of the absence of functional characteristics of the amino-terminal chemokines in the disclosure, to be without merit. Claim 1 encompasses compositions comprising a specific list of chemokines enumerated in the claim. Knowledge of the nucleotide sequence of the chemokines (known in the prior art) coupled with a method of modifying the amino-terminal (provided in the disclosure) allows one of ordinary skill to make and use the invention in a manner commensurate with the scope of the claims.

RESPONSE TO REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 6-9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In making the rejection, the Examiner states the following:

> The rejection of claims 6-9 as indefinite in the recitation of "amino-terminal fragment" and "stringent conditions" is maintained. Fragments are not defined on p. 20; examples are presented but there are no actual limitations as to what constitutes a fragment. Similarly, what is presented on p. 22 is an example, not a definition, of stringent conditions.

Applicants respond as follows:

Applicants respectfully disagree with Examiner 's statements that the terms "fragments" and "stringent hybridizing conditions" are not defined at pp. 20 and 22 of the Specification respectively. The statement at page 20 which states "such fragments retain the desired activity of the amino-terminal-modified chemokine or modify it to create a desired activity" is in fact, a definition of the term "fragments." Similarly lines 12-19 at page 22 provide a definition for the terms "stringent conditions" and "highly stringent conditions." Specific temperatures and salt concentrations of the hybridization and wash buffers are provided in addition to the statement that the hybridizing polynucleotides are required to be at least 70% homologous by sequence identity with the polynucleotide of the present invention to which they hybridize. Therefore, the meanings of the terms "fragments" and "stringent hybridizing conditions" are apparent from the specification, and the metes and bounds of the invention claimed in claims 6-9 can be readily ascertained by one of ordinary skill in the art.

CONCLUSION

Applicant has addressed all of the Examiner's rejections. Based on the arguments above, Applicant believes that all of the claims are now in condition for allowance and respectfully requests that the Examiner grant such an action. If any questions or issues remain in the resolution of which the Examiner feels will be advanced by a conference with the Applicant's attorney, the Examiner is invited to contact the attorney at the number noted below.

It is believed that no fees are due as a result of this Reply. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 10-0447 (Reference No.: 50657-05302USP1).

Respectfully submitted,
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